Adopted	Rejected

COMMITTEE REPORT

YES: 18
NO: 7

MR. SPEAKER:

Your Committee on ***Ways and Means***, *to which was referred* *House Bill 1293*, *has had the same under consideration and begs leave to report the same back to the House with the recommendation that said bill* ***be amended*** *as follows:*

Page 1, between the enacting clause and line 1, begin a new paragraph and insert:

"SECTION 1. IC 12-7-2-22, AS AMENDED BY P.L.272-1999, SECTION 10, IS AMENDED TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2002]: Sec. 22. "Board" means the following:

(1) For purposes of IC 12-10-10 and IC 12-10-11, the community and home options to institutional care for the elderly and disabled board established by IC 12-10-11-1.

(2) For purposes of IC 12-12-7-5, the meaning set forth in IC 12-12-7-5(a).

(3) For purposes of IC 12-15-35, the meaning set forth in IC 12-15-35-2.

(4) **For purposes of IC 12-15-35.5, the meaning set forth in IC 12-15-35.5-1.**

(5) For purposes of IC 12-17-2-36, the meaning set forth in IC 12-17-2-36(a).

SECTION 2. IC 12-15-35-28 IS AMENDED TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2002]: Sec. 28. The board has the following duties:

(1) The adoption of rules to carry out this chapter, in accordance with the provisions of IC 4-22-2 and subject to any office approval that is required by the federal Omnibus Budget Reconciliation Act of 1990 under Public Law 101-508 and its implementing regulations.

(2) The implementation of a Medicaid retrospective and prospective DUR program as outlined in this chapter, including the approval of software programs to be used by the pharmacist for prospective DUR and recommendations concerning the provisions of the contractual agreement between the state and any other entity that will be processing and reviewing Medicaid drug claims and profiles for the DUR program under this chapter.

(3) The development and application of the predetermined criteria and standards for appropriate prescribing to be used in retrospective and prospective DUR to ensure that such criteria and standards for appropriate prescribing are based on the compendia and developed with professional input with provisions for timely revisions and assessments as necessary.

(4) The development, selection, application, and assessment of interventions for physicians, pharmacists, and patients that are educational and not punitive in nature.

(5) The publication of an annual report that must be subject to public comment before issuance to the federal Department of Health and Human Services and to the Indiana legislative council by December 1 of each year.

(6) The development of a working agreement for the board to clarify the areas of responsibility with related boards or agencies, including the following:

(A) The Indiana board of pharmacy.

(B) The medical licensing board of Indiana.

(C) The SURS staff.

(7) The establishment of a grievance and appeals process for physicians or pharmacists under this chapter.

(8) The publication and dissemination of educational information to physicians and pharmacists regarding the board and the DUR program, including information on the following:

(A) Identifying and reducing the frequency of patterns of fraud, abuse, gross overuse, or inappropriate or medically unnecessary care among physicians, pharmacists, and recipients.

(B) Potential or actual severe or adverse reactions to drugs.

(C) Therapeutic appropriateness.

(D) Overutilization or underutilization.

(E) Appropriate use of generic drugs.

(F) Therapeutic duplication.

(G) Drug-disease contraindications.

(H) Drug-drug interactions.

(I) Incorrect drug dosage and duration of drug treatment.

(J) Drug allergy interactions.

(K) Clinical abuse and misuse.

(9) The adoption and implementation of procedures designed to ensure the confidentiality of any information collected, stored, retrieved, assessed, or analyzed by the board, staff to the board, or contractors to the DUR program that identifies individual physicians, pharmacists, or recipients.

(10) The implementation of additional drug utilization review with respect to drugs dispensed to residents of nursing facilities shall not be required if the nursing facility is in compliance with the drug regimen procedures under 410 IAC 16.2-3-8 and 42 CFR 483.60.

(11) The consultation and development with the office of a preferred drug formulary in accordance with IC 12-15-35.5.

SECTION 3. IC 12-15-35.5 IS ADDED TO THE INDIANA CODE AS A **NEW** CHAPTER TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2002]:

Chapter 35.5. Preferred Drug Formulary

Sec. 1. As used in this chapter, "board" refers to the drug utilization review board established by IC 12-15-35-19.

Sec. 2. (a) The office in consultation with the board may develop, establish, and implement a preferred drug formulary in accordance with 42 U.S.C. 1396r-8.

Sec. 3. (a) In establishing the formulary under section 2 of this chapter, the office may negotiate supplemental rebates from manufacturers that are in addition to rebates required under Title XIX of the Social Security Act.

(b) A supplemental rebate under subsection (a) must be at least ten percent (10%) of the average manufacturer price (as defined in 42 U.S.C. 1936) on the last day of a quarter unless:

(1) the federal rebate; or

(2) the federal rebate plus the supplemental rebate;

is more than twenty-four percent (24%) of the average manufacturer price.

(c) A supplemental rebate negotiated by the office under this chapter does not have an upper limit.

Sec. 4. The board or the office may determine that a specific product that is a brand-name drug or generic drug is competitive at a lower rebate percentage.

Sec. 5. An agreement by a drug manufacturer or labeler to pay the minimum supplemental rebate shall guarantee that the specific product of the manufacturer or labeler will be considered by the board and the office for inclusion in the preferred drug formulary; however, a product of the drug manufacturer or labeler that agrees to pay the minimum supplemental rebate for a product is not guaranteed to be placed on the preferred drug formulary.

Sec. 6. A determination by the office of the drugs included on the preferred drug formulary must be based on the following:

(1) The clinical efficacy of the drug.

(2) Recommendations by the board.

(3) The price of competing products less the amount of any federal or state rebate.

Sec. 7. The office may contract with a person to conduct negotiations for supplemental rebates.

Sec. 8. Supplemental rebates may include any of the following:

(1) Cash rebates.

(2) Program benefits that offset Medicaid expenditures, including any of the following:

(A) Disease management programs.

(B) Drug product donation programs.

(C) Drug utilization control programs.

(D) Prescriber and beneficiary counseling and education.

(E) Fraud and abuse initiatives.

(F) Other services or administrative investments that ensure savings to the Medicaid program in the year the rebate reduction is included.

Sec. 9. The office may adopt rules under IC 4-22-2 necessary to implement this chapter.".

Page 2, delete lines 30 through 32, begin a new paragraph and insert:

"**Sec. 2. "Average wholesale price" means the average of the following:**

(1) The wholesale price assigned by a drug manufacturer to a specific commodity that is listed in a nationally recognized drug pricing file.

(2) Supplemental rebates for Medicaid programs above those required under 42 U.S.C. 1396r-8.

(3) Discount prices or rebates for the Indiana prescription drug program established under IC 12-10-16.

(4) Rebates and discounts negotiated for other state programs that pay for or acquire prescription drugs.".

Page 3, between lines 7 and 8, begin a new line block indented and insert:

"**(4) Insured or self funded employee welfare benefit plans described in the federal Employee Retirement Income Security Act (29 U.S.C. 1001 et seq.) that provide prescription drug benefits to residents of Indiana.**".

Page 3, line 38, delete "may" and insert "**shall**".

Page 4, delete lines 18 through 28, begin a new paragraph and insert:

"**(b) When negotiating the amount of the rebate, the state department must consider the following:**

(1) The rebate calculated under the federal Medicaid Rebate Program under 42 U.S.C. 1396r-8.

(2) The price provided to covered entities under 42 U.S.C. 256b.

(3) The national and state averages of all wholesale prices available or negotiated for prescription drugs.

(4) Any other information on prescription drug prices and

price discounts.

(c) The state department and all other units of state government that pay for or acquire prescription drugs shall use their combined knowledge, information, data, and universal best efforts at the same time and same place to maximize the state's ability to obtain a rebate amount that is at least equal to the amount of any discount, rebate, or price reduction for prescription drugs that is provided to the federal government or any other governmental entity that purchases prescription drugs.".

Page 5, line 16, after "the" insert "**best**".

Page 5, delete lines 17 through 18.

Page 5, line 19, delete "THREE" and insert "**TWO**".

Page 5, between lines 27 and 28, begin a new paragraph and insert:

"**(c) In establishing a formula under this section, the state department shall include three (3) varying levels of pricing as follows:**

(1) Uninsured participants shall receive the lowest pricing.

(2) Underinsured participants, including individuals and families, shall receive pricing above the pricing provided to participants under subdivision (1) and less than the pricing provided to participants under subdivision (3).

(3) Participants not described in subdivision (1) or (2) shall receive the highest pricing.".

Page 8, after line 25, begin a new paragraph and insert:

"SECTION 11. [EFFECTIVE JULY 1, 2002] **Recognizing that the state currently acts as a prescription benefits manager for a variety of health plans and assistance programs, IC 16-42.5 is enacted to cover new populations by expanding the state's role as a participant in the free marketplace as it relates to the prescription drug marketplace, just as health maintenance organizations and other large entities participate to negotiate voluntary rebates from drug companies, and use the funds to make prescription drugs more affordable to the state Medicaid program and to state residents. The intent of IC 16-42.5, as added by this act, is to improve public health and welfare, promote the economic strength of the state's citizens, and directly and indirectly benefit the state Medicaid program. IC 16-42.5 is enacted recognizing that the state government is the only agent that, as a practical matter, can be**

effective as a market participant on behalf of all the state's residents who are uninsured, underinsured, Medicaid participants, or taxpayers.

SECTION 12. [EFFECTIVE JULY 1, 2002] **(a) As used in this SECTION, "office" refers to the office of Medicaid policy and planning established under IC 12-8-6-1.**

(b) Before September 1, 2002, the office shall apply to the United States Department of Health and Human Services for approval of any waiver necessary to develop a preferred drug formulary established in IC 12-15-35.5, as added by this act, and in accordance with 42 U.S.C. 1396r-8.

(c) The office may not implement the waiver until the office files an affidavit with the governor attesting that the federal waiver applied for under this SECTION is in effect. The office shall file the affidavit under this subsection not later than five (5) days after the office is notified that the waiver is approved.

(d) If the office receives a waiver under this SECTION from the United States Department of Health and Human Services and the governor receives the affidavit filed under subsection (c), the office shall implement the waiver not more than sixty (60) days after the governor receives the affidavit.".

Renumber all SECTIONS consecutively.

(Reference is to HB 1293 as introduced.)

and when so amended that said bill do pass.

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Representative Bauer